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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,044	04/09/1999	ANDREW H. SOLL	1726-001	8196

9629 7590 09/03/2003

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EXAMINER

RIMELL, SAMUEL G

ART UNIT	PAPER NUMBER
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2175

DATE MAILED: 09/03/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/289,044

Applicant(s)

SOLL ET AL.

Examiner

Sam Rimell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s) ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

SAM RIMELL
PRIMARY EXAMINER

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 39 is are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39: In part (d), the clause "such as" renders the options following the clause indefinite.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al. ('940) in view of Gray ('585).

Claim 23: FIGS 18A-18G disclose a data processing computer which conducts an automated patient interview using programming logic. The interview is setup by the physician using the data entry screen at FIG. 16. The inquiry scope and inquiry depth is dictated by both the physician and the patient. The physician sets up the general scope of inquiry using the screen of FIG. 16 (col 17, lines 44-52). In FIG. 16, the scope of inquiry pertains to injuries of the hand. The answers to the questions provided by the patient will then further dictate the scope and depth of the interview (col. 17, lines 65-67), as answers to questions will dictate which further questions are presented to the patient (col. 18, lines 24-27). ~~The data processing mechanism which receives the answers to the questions will then analyze and prioritize the data so~~ as to

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~~create structured reports (FIGS. 8A and 8B). FIG. 16 is the interview configuration selector~~
~~which allows the physician to select the particular type of interview desired. The steps of setting~~
~~up an interview schedule and designating a primary physician to receive data are inherent~~
~~functions that a physician normally performs when interacting with a patient.~~

~~Claim 23 only differs from Bond et al. in that it does disclose an Internet server to access~~
~~the interview software. However, Gray teaches (FIG. 1) that an Internet web server (130) can~~
~~deliver a patient questionnaire (col. 4, line 44) and permit interactive entry, review and analysis~~
~~of medical data. It would have been obvious to one of ordinary skill in the art to modify Bond et~~
~~al. to deliver patient questionnaires and permit interactive entry, review and analysis of medical~~
~~data so as to permit convenient access to different system users as taught by Gray.~~

TAKE
OUT

Claim 24: Col. 2, line 59 of Gray specifies the inclusion of a user login (password) in order to pass through a security firewall (120) on the network. It would have been obvious to one of ordinary skill in the art to further modify Bond et al. to include password entry as a security precaution as taught by Gray.

Claim 25: FIG. 16 of Bond et al. specifies that the patient interviews are developed from a set of modules (1602, 1602'). Each module corresponds to a specific subject matter area, such as physical symptoms in specific body areas.

Claim 26: Bond et al. teaches that the scope and depth of the interview can be dictated by the physician, using the screen of FIG. 16 (also see col. 17, lines 33-55).

Claim 27-28: The system of Bond et al. permits the physician to set up the interview questions at any time prior to an actual scheduled appointment with the physician. This is

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evidenced by the fact that the patient can answer the questions while sitting in the physician's office (col. 18, lines 37-39).

Claim 29: Any question posed to the patient in Bond et al. reads as a "screening question".

Claim 30: In Bond et al., the length of the interview is constrained by importance of certain medical criteria to the patient. If for example, in FIG. 18F, the patient answers that they are in severe pain, the answer could dictate follow on questions. If the patient indicated no pain, no further follow questions would be needed, thus altering the length of the interview. The length of the interview is also constrained by clinical requirements, such as the clinical selections made in FIG. 16 by the physician.

Claim 31: In Bond et al., the processor utilizes an interview configuration profile. The profile is selected by the physician using the screen selections of FIG. 16.

Claim 32: In Bond et al., any of the questions posed in FIGS. 18A-18G read as patient viewpoint modules since each of these screens presents a question to a patient.

Claim 33: In Bond et al., FIGS. 18A-18G, the patient is queried about multiple symptoms, such as diabetes and hear disease (FIG. 18C); weakness (FIG. 18D) and pain (FIG. 18F).

Claim 34: The system of Bond et al. allows the physician to design the content of a patient interview. Any particular interview which is designed for the patient is readable as an interview configuration profile. As seen in FIG. 16 the system allows "on-off thresholds", which is simply the selection of a particular area of subject matter. As described in claim 25 above, and repeated herein, the system has modules (1602) and (1602') with individual content blocks

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within the module. Any first question posed to a patient is readable as an initial screening question. FIGS. 18A-18H illustrate the potential questions and the questions can pertain to importance of certain items to the patient (FIGS 18E or 18GF) or timing (FIGS. 18A or 18B).

Claim 35: Bond et al. states that the content of an interview may be dictated by specific answers provided by the patient. The specific answers which trigger follow on questions read as content block thresholds. The programming which analyzes and activates these triggers for follow on questions read as the claimed "logical comparator".

Claim 36: As seen in FIGS. 18C, 18D, and 18F of Bond et al., the patient can be queried about multiple symptoms. Since the system asks follow on questions based on specific answers, it is apparent that the system of Bond et al. associates symptoms together and asks more targeted questions as more data is provided. For example, an indication that a patient takes pain medication may lead to associated questions about the exact nature of the pain or location of the pain.

Claim 37: As seen in FIG. 5 of Bond et al., the electronic interview with the patient can collect medical data (510, 512) and psychosocial data (514). FIGS 18A, 18B, 18D, 18E, 18F and 18G in Bond et al. allow for scaled responses by a patient during the interview. The information which is collected is presented to the physician in the form of various types of reports (324 in FIG. 2 and FIGS. 8A and 8B). The data presentation to the physician can take a variety of forms, but one such form illustrated in FIG. 8A involves a probability of meeting a diagnostic threshold.

Claim 38: FIGS 8A and 8B of Bond et al. represent reports to the physician. The data in the report includes various comments about the patient. Any of the numerical data constitutes scores pertaining to the patient. Col. 18, lines 45-53 indicate that the data may be entered

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following repeated visits by the patient, or over time. The scores are thus recalculated as new data as received into the processing system.

Claim 39: Any of the questions posed to the patient in FIGS 18A-18G of Bond et al. are related to quality of life. As seen from col. 18, lines 19-27, the patient may be asked an initial set of screening questions (col. 18, line 20), then, based on the answers to those questions, asked more detailed questions. The line of questioning presented to the patient is thus generic, since there is no rigid questioning routine that must be followed.

Claim 40: Col. 18, lines 47-53 of Bond et al. indicate that the interview may be conducted in one single session or conducted over multiple sessions. The “residual modules” can be any set of questions that are posed at subsequent sessions.

Claim 41: Col. 18, lines 47-53 of Bond et al. describe follow up interviews with the patient. The follow up interviews can be for clinical care.

Claim 42: The information collected at a follow up interview in the Bond et al. system could inherently include change data involving changes in symptoms (col. 18, line 52). Interview questions may be repeated (col. 18, line 49).

Claim 43: In Bond et al., the interview questions may inquire about the status of the patient and changes in symptoms over time (col. 18, lines 51-52). The patient may also be queried about past medical conditions (FIG. 18C). Any of the questions presented to the patient in the screens of 18A-18G pertain to the patient’s quality of life, and thus are considered to be HRQL type questions.

Claim 44: In Bond et al., once the patient data is collected, it is stored in a database for future access. The access to this data is achieved through the physician’s menu page illustrated in

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FIG. 9B. Information about problem areas (button 928), symptoms or medical condition (button 926) can be accessed. As seen in FIG. 9B, the data presentation can be in a medical problem oriented manner (936). The data can be presented by currency (past medical problems by button 928 and current medical problems by button 926). A hierarchy of information and medical problems can be presented (936). Comments by the physician may be entered into the system.

Claim 45: As seen in FIG. 9B of Bond et al., the data presented to the physician may be subjective (930), objective (924, 926, 928), and further include assessments and plans (936).

Claim 46: In FIG. 9B of Bond et al., information on past health information (928) and current health information (926) can be accessed.

Claim 47: FIG. 9B of Bond et al. is a template used by the physician for entering health information. The actions by the physician, such as an examination procedure or treatment procedure can be set up as a menu of protocols and recorded into the database by the physician (See FIG. 13, element 1302 and col. 15, lines 42-45).

Claim 48: In Bond et al., any of the information entered by the physician into the database, such as selected treatment protocol can be printed at a printer to produce a report (114).

Claim 49: As seen in FIG. 10A of Bond et al., the system can maintain a log of examination dates. A log of examination constitutes a schedule, and reads as a programmed mechanism for scheduling. Patient contact information, such as telephone number or address is inherently collected whenever a patient schedules a medical appointment. The contact with the patient may be made by a clinic visit.

Claim 50: As seen in FIG. 6C of Bond et al., steps 628, 634 and 636 define an administrative function where the physician's treatment plan is converted and renamed into

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CPT codes (ICD-9 is a known standard for CPT codes) and generate a list of CPT codes and costs associated with these codes. The list of codes is a “health problem list”. The usage of CPT codes to define and describe medical conditions is a known requirement of JCAHO standard practices.

Claim 51: See remarks for claim 50. The coding is the establishment of the CPT codes for specific treatment provided by the physician. The expense coding is the association of cost with the CPT code, as performed at step 636.

Claim 52: FIG. 18B gives an example interview question. A non-response to the question is not offered as an option. The appropriate responses are already designed by the system. For example, the appropriate responses “Never”, “Occasionally”, “Less than once a day”, “Once a day” and “More than once a day” are already designed into the system.

Claim 53: FIG. 18G in Bond et al. illustrates the collection of quality management data from the patient. This pertains to how satisfied the patient is with the treatment.

Claim 54: The collected quality management data is stored in the database and can be accessed by the physician. The quality management data can be collected after treatment.

Claim 55: The quality management question described by FIG. 18G of Bond et al. probes patient satisfaction.

Claim 56: Within the context of a physical system, no patentable weight is attributed to when the system is being used, such as before a doctor visit or after a doctor visit.

Claim 57: The system of Bond et al. is a patient information system that collects information from patients. The collection system reads as the claimed “mechanism”. Parts (a)-(e)

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appear to be intended usages of the mechanism and methods of using the mechanism which carry no patentable weight in claims addressed to a physical system.

Claim 58: The system of Bond et al., collects data regarding patient assessment, clinical outcomes and patient treatments. How this data is actually used carries no patentable weight in the context of claims addressed to a physical system.

Claim 59: The system of Bond et al. collects and structures patient information and tracks patient responses to questions. How the information is used, such as in a corporate wellness program, carries no patentable weight.

Remarks

With respect to the rejections under 35 USC 112, applicant's amendments have overcome these rejections for all claims except 39. While applicant did amend to overcome a portion of claim 39, applicant did not amend claim 39 to address all of the rejected subject matter in part (d). The remaining basis of rejection under 35 USC 112 is set forth above.

With respect to the rejection under 35 USC 103, applicant's arguments have been considered. In particular, applicant argues that FIG. 16 of Bond et al. does not disclose a system which enables a physician to designate an interview configuration profile, set up patient interview schedules and designate a receiving physician for receiving a patient report.

However, claim 23 does not state that the system of applicant's invention enables the performance or actually performs all of these functions. Claim 23 only states that the data processing mechanism includes an interview configuration profile, and that the physician performs the remaining steps, including designating the profile, setting up the appointments and receiving the reports.

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In the system of Bond et al., the physician designates the desired interview configuration. The functions of making a schedule to interact with the patient and designate who is to receive the data are inherent functions performed by a physician in the interaction with a patient. A physician must schedule a patient interview in order to conduct the interview and must make some indication as to who is going to taking charge of the patient care and review the patient's data. These are inherent and necessary functions performed by a physician.

Examiner maintains that Bond et al. when combined with Gray disclose all of the features as required by claim 23.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

A handwritten signature in black ink, appearing to read 'S. Rimell', is positioned above the printed name.

Sam Rimell
Primary Examiner
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